

## § 556.770

Recorder chart speed: 1 inch per minute.

Sample size: 1 microliter to 5 microliters as necessary to give desired peak area for quantitative measurement.

Septums: Replace each evening and allow to condition overnight at operational temperature.

Flame assembly: Remove silica ash from the flame assembly each week. The flame assembly is removed; the anode, flame jet, and chimney are cleaned with a nylon bristle brush. Water and acetone are drawn through the jet capillary to remove any foreign material.

2. Add 0.2 milliliter of silating reagent to the sample or to the zeranol standard.

3. Stopper the vial and shake vigorously.

4. Warm the vial at 40°-50° C. for a few minutes, then roll the vial on a horizontal plane to insure that all of the interior surfaces of the vial have been in contact with the reagent.

5. Let vial stand for 4 hours or overnight in a warm area (40° C.) to allow reaction to reach completion.

6. Place vial in a small padded centrifuge tube and centrifuge to settle the precipitate and insure that all the liquid is at the bottom of the vial.

7. Inject 1.0-5.0 microliters of clear solution into the chromatograph. At the beginning of the day's run, make 3-5 injections of a standard to condition the column for that day before taking quantitative data.

8. Run known mixtures at the beginning, middle, and end of the day's run over the concentration range of samples to be analyzed to compensate for day-to-day sensitivity fluctuations and drift. If four or less samples are to be run, calibrating at the beginning and end of the run is sufficient.

### VI. CALCULATIONS

Area values are obtained on known mixtures and samples by multiplying the net peak height by the peak width at half height or by counting squares. Area values obtained on knowns are plotted versus zeranol concentration. Calibration plots indicate a near linear function in the 0-10 microgram range. Area values obtained on samples are converted directly to microgram quantities using the curve. Control tests demonstrated a 70 percent recovery of zeranol from spiked wet beef liver and muscle necessitating a correction factor.

$$\text{Zeranol, parts per billion} = \frac{\text{Micrograms of zeranol found A1,000}}{W A0.7}$$

Where:

0.7=Correction factor for 70 percent recovery.

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W=Grams of tissue examined.

### VII. RECOVERY STUDY

A. Fortification of reagent blank.

1. For those using this method for the first time either for recovery study or tissue assay, a solvent blank and solvent fortified with zeranol should be processed through the entire procedure. This preliminary operation will establish whether or not the procedure is free from contamination arising from solvents and glassware and demonstrate the level of recovery of the standard zeranol. Level of recovery should be in the same range as the samples.

2. Transfer 600 milliliters of methanol to a 1-liter beaker. Add 50 milliliters of 2N HCl to the methanol and concentrate to 125 milliliters by boiling on a hot plate.

3. Transfer 600 milliliters of methanol to a 1-liter beaker. Add 50 milliliters of 2N HCl to the methanol and concentrate to 125 milliliters by boiling on a hot plate. Spike the concentrate with 1.0 milliliter of stock solution D.

4. Assay both samples as described in the procedure beginning extraction step V-E1.

B. Fortification of samples.

1. Transfer 100-gram portions of partially thawed tissues into 250-milliliter homogenizing flasks and set half of them aside to serve as tissue blanks.

2. Add to the remaining samples 1 milliliter of stock solution D to serve as fortified samples to which 20 parts per billion zearalanol have been added.

3. Assay both fortified and unfortified tissue as described in the procedure section beginning with V-C1.

[40 FR 13942, Mar. 27, 1975, as amended at 54 FR 31950, Aug. 3, 1989]

## § 556.770 Zoalene.

Tolerances are established for residues of zoalene (3,5-dinitro-*o*-toluamide) and its metabolite 3-amino-5-nitro-*o*-toluamide in food as follows:

(a) In edible tissues of chickens:

(1) 6 parts per million in uncooked liver and kidney.

(2) 3 parts per million in uncooked muscle tissue.

(3) 2 parts per million in uncooked fat.

(b) In edible tissues of turkeys: 3 parts per million in uncooked muscle tissue and liver.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

### Subpart A—General Provisions

Sec.

558.3 Definitions and general considerations applicable to this part.

558.4 Medicated feed applications.

558.5 New animal drug requirements for liquid Type B feeds.

558.15 Antibiotic, nitrofurantoin, and sulfonamide drugs in the feed of animals.

### Subpart B—Specific New Animal Drugs For Use in Animal Feeds

558.35 Aklomide.  
558.55 Amprolium.  
558.58 Amprolium and ethopabate.  
558.59 Apramycin.  
558.60 Arsanilate sodium.  
558.62 Arsanilic acid.  
558.76 Bacitracin methylene disalicylate.  
558.78 Bacitracin zinc.  
558.95 Bambermycins.  
558.105 [Reserved]  
558.115 Carbadox.  
558.120 Carbarsone (not U.S.P.).  
558.128 Chlortetracycline.  
558.145 Chlortetracycline, procaine penicillin, and sulfamethazine.  
558.155 Chlortetracycline, sulfathiazole, penicillin.  
558.175 Clopidol.  
558.185 Coumaphos.  
558.195 Decoquinolate.  
558.205 Dichlorvos.  
558.235 Efrotomycin.  
558.248 Erythromycin thiocyanate.  
558.254 Famphur.  
558.258 Fenbendazole.  
558.265 Halofuginone hydrobromide.  
558.274 Hygromycin B.  
558.295 Iodinated casein.  
558.300 Ivermectin.  
558.305 Laidlomycin propionate potassium.  
558.311 Lasalocid.  
558.315 Levamisole hydrochloride (equivalent).  
558.325 Lincomycin.  
558.340 Maduramicin ammonium.  
558.342 Melengestrol acetate.  
558.348 Mibolerone.  
558.355 Monensin.  
558.360 Morantel tartrate.  
558.363 Narasin.  
558.365 Nequinolate.  
558.366 Nicarbazine.  
558.367 Niclosamide.  
558.369 Nitarsone.  
558.376 Nitromide and sulfantran.  
558.415 Novobiocin.  
558.430 Nystatin.  
558.435 Oleandomycin.  
558.450 Oxytetracycline.

558.460 Penicillin.  
558.464 Poloxalene.  
558.465 Poloxalene free-choice liquid Type C feed.  
558.485 Pyrantel tartrate.  
558.515 Robenidine hydrochloride.  
558.525 Ronnel.  
558.530 Roxarsone.  
558.550 Salinomycin.  
558.555 Sempduramicin.  
558.565 Styrylpyridinium chloride, diethylcarbamazine.  
558.575 Sulfadimethoxine, ormetoprim.  
558.579 Sulfathiazole.  
558.582 Sulfamerazine.  
558.586 Sulfamonomycin.  
558.600 Tiamulin.  
558.615 Thiabendazole.  
558.625 Tylosin.  
558.630 Tylosin and sulfamethazine.  
558.635 Virginiamycin.  
558.680 Zoalene.

AUTHORITY: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

SOURCE: 40 FR 13959, Mar. 27, 1975, unless otherwise noted.

### Subpart A—General Provisions

#### § 558.3 Definitions and general considerations applicable to this part.

(a) Regulations in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross-reference. Unless specifically provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) New animal drugs approved for use in animal feed are placed in two categories as follows:

(i) Category I—These drugs require no withdrawal period at the lowest use level in each species for which they are approved.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved or are regulated on a “no-residue” basis or with a “zero” tolerance because of a carcinogenic concern regardless whether a withdrawal period is required.